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Dosing Commences in Clinical Trial of ATL1103

- **First human subject dosed in Phase I trial of ATL1103**
- **Cancer experimental program to run in parallel with Phase I clinical trial**

Antisense Therapeutics Limited (ASX:ANP) is pleased to advise that the dosing of human subjects has now commenced in the Phase I trial of the Company's growth hormone receptor (GHr) targeting drug ATL1103. The Phase I trial is being run by Nucleus Network (a leading Australian Clinical Research Organization) at their dedicated clinical trial unit co-located at the Austin Hospital, Heidelberg, Victoria.

The trial is a randomized, placebo controlled, double blind study of single ascending doses and multiple doses of ATL1103 in healthy adult male subjects aged between 18 and 45 years. The primary objective of the study is to assess the safety, tolerability and pharmacokinetics of ATL1103 administered by subcutaneous (under the skin) injection.

A secondary, but important objective of this study, is to obtain key data on the effect of ATL1103 on IGF-I levels in the blood of the trial subjects. Reducing elevated levels of serum IGF-I to normal is the therapeutic endpoint in the treatment of the growth disorder acromegaly, and reducing the effects of IGF-I has a potential role in the treatment of diabetic retinopathy, nephropathy and certain forms of cancer. In pre-clinical studies, ATL1103 was shown to significantly suppress serum IGF-I levels in both mice and primates.

Approximately 36 subjects will be enrolled to participate in the Phase I clinical trial (24 in the single ascending dose stage and 12 in the multiple dose stage). In the single ascending dose stage of the trial, up to four dose levels starting at 25mg, and escalating to 75, 250 and 400 mg will be administered as a subcutaneous injection. Based on a review of the safety data from the single ascending dose stage, one dose level will be selected for the multiple dose component of the study. Multiple dosing will consist of six once – daily subcutaneous doses over 21 days on Days 1, 3, 5, 7, 14 and 21). Subjects will be monitored out to Day 35.

The Company is also pleased to advise that Professor George Werther, non executive Director of Antisense Therapeutics and Director of Endocrinology at The Royal Children's Hospital and Director of the Centre for Hormone Research at the Murdoch Childrens Research Institute, will be a member of the data monitoring committee (DMC) for the ATL1103 Phase I trial. The DMC's responsibilities include reviewing the available safety data to enable decision making pertaining to dose escalation and any safety related decisions on the trial such as subject withdrawal etc.

Along with expert advice provided on the project by Professor Werther, the Company is also consulting with Professor Shlomo Melmed from the School of Medicine at UCLA and Director of Cedars-Sinai Research Institute and Dean of the Medical Faculty of Cedars-Sinai Medical Centre, CA. Professor Melmed is an endocrinologist, editor in chief of several prestigious endocrinology journals and recognized global opinion leader in the field of acromegaly.

Professor Melmed added "There is a need for improved therapies for treatment of the growth disorder, acromegaly. ATL1103's effects in suppressing serum IGF-I levels in previous studies combined with its potential safety advantages over existing treatments and more convenient dosing regimen make ATL1103 an excellent clinical candidate. This Phase I study aims to establish ATL1103's safety and effects on serum IGF-I in humans and thereby validate its clinical potential in acromegaly and other relevant disease applications".

Dosing in both the single ascending and multiple dose stages of the Phase I trial is expected to be completed before the end of the year with the database lock occurring in Q1 2012.

ATL1103 Cancer Experimental Program

ANP will also be undertaking its ATL1103 cancer experimental program in parallel with the conduct of the Phase I clinical trial outlined above. The ATL1103 cancer experimental program has been established with leading expert Dr Pinchas Cohen M.D., Professor and Chief of Diabetes and Endocrinology, Mattel Children's Hospital at UCLA.

Professor Cohen co-authored a study that found that patients with Laron syndrome who carry a genetic mutation that silences their GHr thereby having depressed levels of GHr and IGF-I, were protected from developing cancer. The authors of the study tested serum samples from this population and found that these samples induced higher levels of cellular protection and resulted in decreased proliferation and reduced expression of specific pro-growth signaling genes, which regulate growth, promote ageing and lead to activation of processes that may lead to cancer progression.

Professor Cohen's laboratory team will look at ATL1103's effect on exploratory markers of cellular activity relevant to cancer in the serum of the subjects from the Phase I trial of ATL1103 who have received multiple doses of ATL1103. This data will assist in determining the potential of ATL1103 in the new application of preventing certain forms of cancer in high risk individuals.

Background Information

ATL1103 is a second generation antisense drug designed to block growth hormone receptor (GHr) expression thereby reducing levels of the hormone insulin-like growth factor-I (IGF-I) in the blood and is a potential treatment for diseases associated with excessive growth hormone and IGF-I action. These diseases include acromegaly, an abnormal growth disorder of organs, face, hands and feet, diabetic retinopathy, a common disease of the eye and a major cause of blindness, diabetic nephropathy and some forms of cancer. Acromegalic patients are known to have significantly higher blood IGF-I levels than healthy individuals. Reduction of these levels to normal is accepted by clinical authorities as the primary marker of an effective drug treatment for the disease. GHr is a clinically validated target in the treatment of acromegaly. In the case of diabetic retinopathy, published clinical studies have shown that treatments producing a reduction in IGF-I levels retarded the progression of the disease and improve vision in patients. ANP have published scientific papers demonstrating suppression of blood IGF-I levels in the mouse and inhibition of retinopathy in a mouse retinopathy model using an antisense drug to the GHr (Wilkinson-Berka et al., 2007, Molecular Vision 13, 1529- 38;Tachas et al., 2006, J Endocrinol 189, 147-54) and ANP have previously reported that ATL1103 injection suppressed circulating levels of IGF-I in primates and that toxicology studies have been completed supporting the Company's plans to move ATL1103 into clinical development. ATL1103 commercialisation is covered by patent to at least 2024, with the potential for extensions up to 2029 in some countries and 2030 in the US.

Antisense Therapeutics Limited (ASX: ANP) is an Australian publicly listed biopharmaceutical drug discovery and development company. Its mission is to create, develop and commercialise second generation antisense pharmaceuticals for large unmet markets. ANP has two drugs in development and two drugs in pre-clinical research. ATL1102 (injection) has successfully completed a Phase II efficacy and safety trial, significantly reducing the number of MRI lesions in patients with multiple sclerosis. ATL1103 is a second-generation antisense drug designed to block GHr production and thereby lower blood IGF-I levels and is entering the clinical stage of development as a potential treatment for growth and vision disorders. ATL1102 (inhaled) is at the pre-clinical research stage as a potential treatment for asthma. ATL1101 is a second-generation antisense drug at the pre-clinical stage being investigated as a potential treatment for prostate cancer.

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